procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) *Other personnel.* Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) *Training.* The laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* Laboratory personnel files shall include: resume of training and experience, certification or license if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

§ 40.29 Laboratory analysis procedures.

(a) *Security and chain of custody.* (1) Drug testing laboratories shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory process or to areas where records are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of Federal agencies for which the laboratory is engaged in urine testing or on behalf of DHHS, all authorized visitors and maintenance and service personnel shall be escorted at all times. Documentation of individuals accessing these areas, dates, and time of entry and purpose of entry must be maintained.

(2) Laboratories shall use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

(b) *Receiving.* (1)(i) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and the employer's chain of custody forms attached to the shipment shall be immediately reported to the employer and shall be noted on the laboratory's chain of custody form which shall accompany the specimens while they are in the laboratory's possession.

(ii) Where the employer has used the split sample method, and the laboratory observes that the split specimen is untestable, inadequate, or unavailable for testing, the laboratory shall nevertheless test the primary specimen. The laboratory does not inform the MRO or the employer of the untestability, inadequacy, or unavailability of the split specimen until and unless the primary specimen is a verified positive test and the MRO has informed the laboratory that the employee has requested a test of the split specimen.

(2) In situations where the employer uses the split sample collection method, the laboratory shall log in the split specimen, with the split specimen bottle seal remaining intact. The laboratory shall store this sample securely (see paragraph (c) of this section). If the result of the test of the primary specimen is negative, the laboratory may discard the split specimen. If the result of the test of the primary specimen is positive, the laboratory shall retain the split specimen in frozen storage for 60 days from the date on which the laboratory acquires it (see

paragraph (h) of this section). Following the end of the 60-day period, if not informed by the MRO that the employee has requested a test of the split specimen, the laboratory may discard the split specimen.

(3) When directed in writing by the MRO to forward the split specimen to another DHHS-certified laboratory for analysis, the second laboratory shall analyze the split specimen by GC/MS to reconfirm the presence of the drug(s) or drug metabolite(s) found in the primary specimen. Such GC/MS confirmation shall be conducted without regard to the cutoff levels of §40.29(f). The split specimen shall be retained in long-term storage for one year by the laboratory conducting the analysis of the split specimen (or longer if litigation concerning the test is pending).

(c) *Short-term refrigerated storage.* Specimens that do not receive an initial test within 7 days of arrival at the laboratory shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. Emergency power equipment shall be available in case of prolonged power failure.

(d) *Specimen processing.* Laboratory facilities for urine drug testing will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts.

(e) *Initial test.* (1) The initial test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these five drugs or classes of drugs:

	Initial test cutoff levels (ng/ml)
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites	2000
Phencyclidine	25
Amphetamines	1,000

(2) These cutoff levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations.

(f) *Confirmatory test.* (1) All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cutoff levels listed in this paragraph for each drug. All confirmations shall be by quantitative analysis. Concentrations that exceed the linear region of the standard curve shall be documented in the laboratory record as ''greater than highest standard curve value.''

	Confirmatory test cutoff levels (ng/ml)
Marijuana metabolite [1]	15
Cocaine metabolite [2]	150
Opiates	
Morphine	2000
Codeine	2000
6-Acetylmorphine [4]	10 ng/ml.
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine [3]	500

[1] Delta-9-tetrahydrocannabinol-9-carboxylic acid.
[2] Benzoylecgonine.
[3] Specimen must also contain amphetamine at a concentration greater than or equal to 200 ng/ml.
[4] Test for 6–AM when morphine concentration exceeds 2,000 ng/ml.

(2) These cutoff levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations.

(g) *Reporting results.* (1) The laboratory shall report test results to the employer's Medical Review Officer within an average of 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual. The report shall identify the drugs/metabolites tested for,

whether positive or negative, the specimen number assigned by the employer, and the drug testing laboratory specimen identification number (accession number).

(2) The laboratory shall report as negative all specimens that are negative on the initial test or negative on the confirmatory test. Only specimens confirmed positive shall be reported positive for a specific drug.

(3) The Medical Review Officer may request from the laboratory and the laboratory shall provide quantitation of test results. The MRO shall report whether the test is positive or negative, and may report the drug(s) for which there was a positive test, but shall not disclose the quantitation of test results to the employer. *Provided*, that the MRO may reveal the quantitation of a positive test result to the employer, the employee, or the decisionmaker in a lawsuit, grievance, or other proceeding initiated by or on behalf of the employee and arising from a verified positive drug test.

(4) The laboratory may transmit results to the Medical Review Officer by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The laboratory and employer must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the Medical Review Officer the original or a certified true copy of the drug testing custody and control form (part 2), which, in the case of a report positive for drug use, shall be signed (after the required certification block) by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports, and attached to which shall be a copy of the test report.

(6) The laboratory shall provide the employer an aggregate quarterly statistical summary of urinalysis testing of the employer's employees. Laboratories may provide the report to a consortium provided that the laboratory provides employer-specific data and the consortium forwards the employer-specific data to the respective employers within 14 days of receipt of the laboratory report. The laboratory shall provide the report to the employer or consortium not more than 14 calendar days after the end of the quarter covered by the summary. Laboratory confirmation data only shall be included from test results reported within that quarter. The summary shall contain only the following information:

(i) Number of specimens received for testing;

(ii) Number of specimens confirmed positive for—

(A) Marijuana metabolite

(B) Cocaine metabolite

(C) Opiates;

(D) Phencyclidine;

(E) Amphetamines;

(iii) Number of specimens for which a test was not performed.

Quarterly reports shall not contain personal identifying information or other data from which it is reasonably likely that information about individuals' tests can be readily inferred. If necessary, in order to prevent disclosure of such data, the laboratory shall not send such a report until data are sufficiently aggregated to make such an inference unlikely. In any quarter in which a report is withheld for this reason, or because no testing was conducted, the laboratory shall so inform the consortium/employer in writing.

(7) The laboratory shall make available copies of all analytical results for employer drug testing programs when requested by DOT or any DOT agency with regulatory authority over the employer.

(8) Unless otherwise instructed by the employer in writing, all records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

(h) *Long-term storage.* Long-term frozen storage (· 20°C or less) ensures that positive urine specimens will be available for any necessary retest during administrative or disciplinary proceedings. Drug testing laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive, in their original labeled specimen bottles. Within this 1-

year period, an employer (or other person designated in a DOT agency regulation) may request the laboratory to retain the specimen for an additional period of time, but if no such request is received the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens known to be under legal challenge for an indefinite period.

(i) *Retesting specimens.* Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cutoff requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(j) *Subcontracting.* Drug testing laboratories shall not subcontract and shall perform all work with their own personnel and equipment. The laboratory must be capable of performing testing for the five classes of drugs (marijuana, cocaine, opiates, phencyclidine and amphetamines) using the initial immunoassay and confirmatory GC/MS methods specified in this part. This paragraph does not prohibit subcontracting of laboratory analysis if specimens are sent directly from the collection site to the subcontractor, the subcontractor is a laboratory certified by DHHS as required in this part, the subcontractor performs all analysis and provides storage required under this part, and the subcontractor is responsible to the employer for compliance with this part and applicable DOT agency regulations as if it were the prime contractor.

(k) *Laboratory facilities.* (1) Laboratory facilities shall comply with applicable provisions of any State licensing requirements.

(2) Laboratories certified in accordance with DHHS Guidelines shall have the capability, at the same laboratory premises, of performing initial and confirmatory tests for each drug or metabolite for which service is offered.

(l) *Inspections.* The Secretary, a DOT agency, any employer utilizing the laboratory, DHHS or any organization performing laboratory certification on behalf of DHHS reserves the right to inspect the laboratory at any time. Employer contracts with laboratories for drug testing, as well as contracts for collection site services, shall permit the employer and the DOT agency of jurisdiction (directly or through an agent) to conduct unannounced inspections.

(m) *Documentation.* The drug testing laboratories shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2 year period may be extended upon written notification by a DOT agency or by any employer for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The laboratory shall maintain documents for any specimen known to be under legal challenge for an indefinite period.

(n) *Additional requirements for certified laboratories.*—(1) *Procedure manual.* Each laboratory shall have a procedure manual which includes the principles of each test preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of methods, cutoff values, mechanisms for reporting results, controls criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) *Standards and controls.* Laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates: when received; when prepared or opened; when placed in service; and expiration date.

(3) *Instruments and equipment.* (i) Volumetric pipettes and measuring devices shall be certified for accuracy or

be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks and instructions for major trouble shooting and repair. Records shall be available on preventive maintenance.

(4) *Remedial actions.* There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) *Personnel available to testify at proceedings.* A laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against an employee when that proceeding is based on positive urinalysis results reported by the laboratory.

(6) The laboratory shall not enter into any relationship with an employer's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having an employer use a specific MRO.

[54 FR 49866, Dec. 1, 1989, as amended at 59 FR 7356, Feb. 15, 1994; 59 FR 43001, Aug. 19, 1994; 63 FR 65129, Nov. 25, 1998]

§ 40.31 Quality assurance and quality control.

(a) *General.* Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody security and reporting of results, initial and confirmatory testing and validation of analytical procedures. Quality assurance procedures shall be designed, implemented and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) *Laboratory quality control requirements for initial tests.* Each analytical run of specimens to be screened shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the cutoff level.

In addition, with each batch of samples a sufficient number of standards shall be included to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Implementation of procedures to ensure the carryover does not contaminate the testing of an individual's specimen shall be documented. A minimum of 10 percent of all test samples shall be quality control specimens. Laboratory quality control samples, prepared from spiked urine samples of determined concentration shall be included in the run and should appear as normal samples to laboratory analysts. One percent of each run, with a minimum of at least one sample, shall be the laboratory's own quality control samples.

(c) *Laboratory quality control requirements for confirmation tests.* Each analytical run of specimens to be confirmed shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

(3) Positive controls with the drug or metabolite at or near the cutoff level. The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(d) *Employer blind performance test procedures.* (1) Each employer covered by DOT agency drug testing regulations shall use blind testing quality control procedures as provided in this paragraph.

(2) Each employer shall submit three blind performance test specimens for each 100 employee specimens it submits, up to a maximum of 100 blind performance test specimens submitted per quarter. A DOT agency may increase